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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/560,303  | 03/29/2007  | Masayori Inouye      | 601-I-131PCTUS      | 9634             |
| 23565 7590 01/29/2011<br>KLAUBER & JACKSON<br>411 HACKENSACK AVENUE<br>HACKENSACK, NJ 07601 |             |                      |                     |                  |
| EXAMINER<br>HIBBERT, CATHERINE S  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/560,303

**Applicant(s)**

INOUE ET AL.

**Examiner**

CATHERINE HIBBERT

**Art Unit**

1636

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24 and 29-31 is/are rejected.
- 7) ☒ Claim(s) 25-28 and 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's submission filed 2 November 2010 is received and entered. Applicant's Amendment to the Claims filed 2 November 2010 is received and entered. This US Application 10/560,303 filed 12 December 2005, which is a national stage entry of PCT/US04/18571, filed 14 June 2004, claims benefit of US Provisional Applications 60/478,515 filed 6/13/2003 and 60/543,693 filed 2/11/2004. Claims 1-23 and 33-35 are cancelled. Claims 24-32 are pending. Claims 24-32 are under examination in this action.

### **Election/Restrictions**

In view of claim amendments filed 2 November 2010, the species election requirement between the species "ACA" versus "UAX" as the type of recognition sequence and "MazF comprising SEQ ID NO:2 versus PemK comprising SEQ ID NO:4 as the type of mRNA interferase is WITHDRAWN herein and therefore claims 26 and 28 are being rejoined and examined herein.

Any objections and rejections not repeated herein are withdrawn.

The objection to the Drawings is withdrawn based on Applicant's persuasive argument.

### **Response to Amendments**

#### **Claim Rejections - 35 USC § 112-maintained-in-part**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 29-31 STAND rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record and below.

Claims are drawn to a method for making a polypeptide, the method comprising: (a) transfecting into a cell/providing a nucleic acid sequence encoding said polypeptide, wherein the nucleic acid sequence encoding said polypeptide is mutated to replace mRNA interferase recognition sequences with an alternate triplet codon, wherein amino acid sequences of said polypeptide encoded by said mutated nucleic acid sequence are not altered by said mutating;(b) transfecting into a cell/providing a nucleic acid sequence encoding an mRNA interferase, wherein said mRNA interferase recognizes said mRNA interferase recognition sequences; and (c) expressing the nucleic acid sequences of step (a) and (b), wherein expressing the nucleic acid sequences of step (a) and (b) produces the polypeptide in said cell. Thus, the applicant claims methods that require “a nucleic acid sequence encoding an mRNA interferase, wherein said mRNA interferase recognizes said mRNA interferase recognition sequences” as a materially essential element to the claimed method. It is noted that the instant specification discloses that the term mRNA interferase is intended to encompass unknown homologs and orthologs of the two identified mRNA interferases, MazF and PemK (e.g. paragraph 0009) and specifically to include unknown functional fragments of SEQ ID NO:2 and/or SEQ ID NO:4. Thus, the claims encompass methods using unknown functional sequences relating to homologs and orthologs of mRNA interferases and particularly unknown functional fragments of SEQ ID NO:2 and/or SEQ

ID NO:4. Thus, the claims read on methods that require a broad genus of sequences that can perform the function of recognizing the mRNA interferase recognition sequences.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the claimed invention. In the instant case, the specification does not sufficiently describe a representative number of homologs and orthologs of the two identified mRNA interferases, MazF and PemK or functional fragments of SEQ ID NO:2 and/or SEQ ID NO:4 by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims homologs and orthologs of the two identified mRNA interferases, MazF and PemK, without any disclosed or known correlation between the required sequence elements and their function. The specification only provides teachings of SEQ ID NO:2 and/or SEQ ID NO:4. The specification does not teach how to mutate SEQ ID NO:2 and/or SEQ ID NO:4 and still have it function. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses functional SEQ ID NO:2 and/or SEQ ID NO:4.

The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the art that allows one to envision a representative number of functional homologs and orthologs of

the two identified mRNA interferases, MazF and PemK or of functional fragments of SEQ ID NO:2 and/or SEQ ID NO:4 by disclosing structural or functional features that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot consult the art at the time of filing to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the state of the art at the time of filing teaches a structure-function relationship for a representative number of functional sequence fragments. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

**Applicant's response** presented in the Remarks filed on 11/02/2010 has been fully considered but is unpersuasive regarding claims 24 and 29-31. The rejection of claims 25, 27 and 32 is withdrawn based on claim amendments.

Applicant's response is to traverse the rejection. Applicant argues that claims 25 and 32 are currently amended to remove the phrase "or a functional fragment thereof" and that therefore these amendments have overcome the rejection of claims 24, 25, 27 and 29-32. While Examiner agrees that the amendments are sufficient to overcome the rejection of claims 25 and 32, the amendments do not apply to the generic claims which still encompass the sequences of unknown functional homologs and orthologs of the two identified mRNA interferases, MazF and PemK or of functional fragments of SEQ ID NO:2 and/or SEQ ID NO:4. In addition, it is noted for clarity

of the record that, as stated in the interview summary mailed 11/8/2010, the examiner discussed that the deletion of the phrase "or a functional fragment thereof" from claim 25 would overcome the written description rejection of claim 25 but did not indicate that this claim amendment would overcome the rejection of the other claims including the base claims.

Therefore, claims 24 and 29-31 STAND rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### **Allowable Subject Matter**

Claims 25-28 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **Conclusion**

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joanne Hama can be reached on 571-272-2911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

Catherine Hibbert  
Examiner AU1636